



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IFW

In re Applicant:

Shmuel PIETROKOVSKI et al

Serial No.: 10/534,544

Filed: May, 10, 2005

For: CHIMERIC AUTOPROCESSING POLYPEPTIDES  
AND USES THEREOF

Examiner: Not Yet Assigned

§  
§  
§  
§  
§  
§  
§  
§  
§  
§

Group Art Unit: 1645

Attorney  
Docket: 29489

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Enclosed is a PTO Form 1449 which lists citations which may be material to the patentability and examination of the above identified application. Also enclosed are copies of the references cited. These are submitted in compliance with the duty of disclosure defined in 37 CFR 1.56. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement under 37 CFR 1.56 is not to be construed as a representation that a search has been made, that additional matter which is material to the examination of this application does not exist, or that any or more of these citations constitutes prior art.

Respectfully submitted,

Martin D. Moynihan  
Registration No. 40,338

Dated: January 23, 2007



PTO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p>				Complete if Known	
				Application Number	10/534,544
				Filing Date	May, 10, 2005
				First Named Inventor	Shmuel PIETROKOVSKI et al
				Group Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	1	Of	4	Attorney Docket Number	29489
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	1	Amitai et al. "Distribution and Function of New Bacterial Intein-Like Protein Domains", Molecular Microbiology, 47(1): 61-73, 2003.			
	2	Fraser et al. "Novel Neisserial Polypeptides Predicted to Be Useful Antigens for Vaccines and Diagnostics", Database EMBL 'Online!', No. AAY75498, 2000.			
	3	Zhang et al "Construction of A Mini-Intein Fusion System to Allow Both Direct Monitoring of Soluble Protein Expression and Rapid Purification of Target Proteins", Gene, 275(2): 241-252, 2001. P.250, l-h Col., § 3 - P.251, r-h Col., § 1, Figs.1, 3.			
	4	Humphries et al. "Expression of the Class 1 Outer-Membrane Protein of Neisseria Meningitidis in Escherichia Coli and Purification Using A Self-Cleavable Affinity Tag", Protein Expression and Purification, 26(2): 243-248, 2002. P.247, r-h Col., § 2 - P.248, l-h Col., § 2, Fig.1.			
	5	Aspöck et al. "Caenorhabditis Elegans Has Scores of Hedgehog-Related Genes: Sequence and Expression Analysis", Genome Research, 9(10): 909-923, 1999.			
	6	Petrokovski "Intein Spread and Extinction in Evolution", Trends in Genetics 17(8): 465-472, 2001.			
	7	Buell et al. "Filamentous Hemagglutinin, Intein-Containing, Putative", Database Trembl 'Online!', No. Q880E1, 2003.			
	8	Brown et al. "Hypothetical Protein SCP1.201", Database Trembl 'Online!', No. Q9ACV2, 2003.			
	9	Ren "Probable Phenazine Biosynthesis Family Protein", Database Trembl 'Online!', No. Q8EZK6, 2003.			
	10	Gloeckner et al. "Hypothetical Protein RB6107", Database Trembl 'Online!', No. Q7UQT4, 2003.			
	11	Omura et al. "Hypothetical Protein SAV200", Database Trembl. 'Online!', No. Q82RE3, 2003.			
	12	Omura et al. "Hypothetical Protein SAV286", Database Trembl. 'Online!', No. Q82R58, 2003.			
	13	Omura et al. "Hypothetical Protein SAV5292", Database Trembl 'Online!', No. Q82CQ1, 2003.			
	14	Ren "Hypothetical Protein LA3719", Database Trembl 'Online!', No. Q8EZY2, 2003.			
	15	Dassa et al. "Protein Splicing and Auto-Cleavage of Bacterial Intein-Like Domains Lacking A C'-Flanking Nucleophilic Residue", The Journal of Biological Chemistry, 279(31): 32001-32007, 2004.			
	16	Dassa et al. "New Type of Polyubiquitin-Like Genes With Intein-Like Autoprocessing Domains", Trends in Genetics, 20(11): 538-542, 2004.			
Signature		Considered			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>. Applicant's unique citation designation number (optional). <sup>2</sup>. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. this collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/534,544		
		Filing Date	May, 10, 2005		
		First Named Inventor	Shmuel PIETROKOVSKI et al		
		Group Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	2	Of	4	Attorney Docket Number	29489
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
	17	Southworth et al. "Rescue of Protein Splicing Activity From A Magnetospirillum Magnetotacticum Intein-Like Element", Biochemical Society Transactions, 32(Part 2): 250-254, 2004.			
	18	Dassa et al. "Origin and Evolution of Inteins and Other Hint Domains", Nucleic Acids and Molecular Biology, 16: 209-229, 2005.			
	19	Belfort et al. "Homing Endonucleases: Keeping the House in Order", Nucleic Acids Research, 25(17): 3379-3388, 1997.			
	20	Bürglin "Warthog and Groundhog, Novel Families Related to Hedgehog", Current Biology, 6(9): 1047-1950, 1996.			
	21	Cattoli et al. "Separation of MBP Fusion Proteins Through Affinity Membranes", Biotechnological Progresses, 18(1): 94-100, 2002.			
	22	Chong et al. "Protein Splicing Involving the Saccharomyces Cerevisiae VMA Intein", The Journal of Biological Chemistry, 271(36): 22159-22168, 1996.			
	23	Chong et al. "Single-Column Purification of Free Recombinant Proteins Using A Self-Cleavable Affinity Tag Derived From A Protein Splicing Element", Gene, 192: 271-281, 1997.			
	24	Chong et al. "Protein Splicing of the Saccharomyces Cerevisiae VMA Intein Without the Endonuclease Motifs", The Journal of Biological Chemistry, 272(25): 15587-15590, 1997.			
	25	Chong et al. "Modulation of Protein Splicing of the Saccharomyces Cerevisiae Vacuolar Membrane ATPase Intein", The Journal of Biological Chemistry, 273(17): 10567-10577, 1998.			
	26	Chong et al. "Utilizing the C-Terminal Cleavage Activity of A Protein Splicing Element to Purify Recombinant Proteins in A Single Chromatographic Step", Nucleic Acids Research, 26(22): 5109-5115, 1998.			
	27	Clonis "High-Performance Affinity Chromatography (HPAC)", HPLC of Macromolecules: A Practical Approach, IRL Press, Chap.6: 157-182, 1989.			
	28	Coote "Structural and Functional Relationships Among the RTX Toxin Determinants of Gram-Negative Bacteria", FEMS Microbiology Reviews, 88: 137-162, 1992.			
	29	Dalgaard et al. "Statistical Modeling, Phylogenetic Analysis and Structure Prediction of A Protein Splicing Domain Common to Inteins and Hedgehog Proteins", Journal of Computational Biology, 4(2): 193-214, 1997.			
	30	Derbyshire et al. "Genetic Definition of A Protein-Splicing Domain: Functional Mini-Inteins Support Structure Predictions and A Model for Intein Evolution", Proc. Natl. Acad. Sci. USA, 94: 11466-11471, 1997.			
	31	Fouts et al. "Genomewide Identification of Pseudomonas Syringae Pv. Tomato DC3000 Promoters Controlled by the HrpL Alternative Sigma Factor", Proc. Natl. Acad. Sci. USA, 99(4): 2275-2280, 2002.			
	32	Gimble et al. "Homing of A DNA Endonuclease Gene by Meiotic Gene Conversion in Saccharomyces Cerevisiae", Nature, 357(6376): 301-306, 1992.			
Signature		Considered			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>. Applicant's unique citation designation number (optional). <sup>2</sup>. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/534,544
				Filing Date	May, 10, 2005
				First Named Inventor	Shmuel PIETROKOVSKI et al
				Group Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	3	Of	4	Attorney Docket Number	29489
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
	33	Guan et al. "Production of Extracellular Domain of Human Tissue Factor Using Maltose-Binding Protein Fusion System", Protein Expression and Purification, 26: 229-234, 2002.			
	34	Tanaka Hall et al. "Crystal Structure of A Hedgehog Autoprocessing Domain: Homology Between Hedgehog and Self-Splicing Proteins", Cell, 91: 85-97, 1997.			
	35	Hammerschmidt et al. "The World According to Hedgehog", Trends in Genetics, 13(1): 14-21, 1997.			
	36	Haselkorn et al. "The Rhodobacter Capsulatus Genome", Photosynthesis Research, 70: 43-52, 2001.			
	37	Hirata et al. "Molecular Structure of A Gene, VMA1, Encoding the Catalytic Subunit of H <sup>+</sup> -Translocating Adenosine Triphosphatase From Vacuolar Membranes of Saccharomyces Cerevisiae", The Journal of Biological Chemistry, 265(12): 6726-6733, 1990.			
	38	Jack "Immunoaffinity Chromatography", Molecular Biotechnology, 1: 59-86, 1994.			
	39	James et al. "The Biology of E Colicins: Paradigms and Paradoxes", Microbiology, 142: 1569-1580, 1996.			
	40	Janson et al. "Packings in Affinity Chromatography", Techniques, P.747-781, 1990.			
	41	Jensen et al. "Delayed Extraction Improves Specificity in Database Searches by Matrix-Assisted Laser Desorption/Ionization Peptide Maps", Rapid Communications in Mass Spectrometry, 10: 1371-1378, 1996.			
	42	Kane et al. "Protein Splicing Converts the Yeast TFP1 Gene Product to the 69-KD Subunit of the Vacuolar H <sup>+</sup> -Adenosine Triphosphatase", Science, 250(4981): 651-657, 1990.			
	43	Kaufmann et al. "Crystal Structure of the Anti-His Tag Antibody 3D5 Single-Chain Fragment Complexed to Its Antigen", Journal of Molecular Biology, 318: 135-147, 2002.			
	44	Kusmann et al. "Matrix-Assisted Laser Desorption/Ionization Mass Spectrometry Sample Preparation Techniques Designed for Various Peptide and Protein Analytes", Journal of Mass Spectrometry, 32: 593-601, 1997.			
	45	Narayanan "Preparative Affinity Chromatography of Proteins", Journal of Chromatography A, 658: 237-258, 1994.			
	46	Nilsson et al. "Affinity Fusion Strategies for Detection, Purification, and Immobilization of Recombinant Proteins", Protein Expression and Purification, 11: 1-16, 1997.			
	47	Nisnevitch et al. "The Solid Phase in Affinity Chromatography: Strategies for Antibody Attachment", Journal of Biochemical and Biophysical Methods, 49: 467-480, 2001.			
	48	Noren et al. "Dissecting the Chemistry of Protein Splicing and Its Applications", Angewandte Chemie, International Edition, 39: 450-466, 2000.			
Signature					
Considered					

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>. Applicant's unique citation designation number (optional). <sup>2</sup>. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office,

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/534,544
				Filing Date	May, 10, 2005
				First Named Inventor	Shmuel PIETROKOVSKI et al
				Group Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	4	Of	4	Attorney Docket Number	29489
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
49	Paulus "Protein Splicing and Related Forms of Protein Autoprocessing", Annual Review of Biochemistry, 69: 447-496, 2000.				
50	Perler et al. "Protein Splicing and Its Applications", Current Opinion in Biotechnology, 11: 377-383, 2000.				
51	Perler et al. "Protein Splicing Elements: Inteins and Exteins - A Definition of Terms and Recommended Nomenclature", Nucleic Acids Research, 22(7): 1125-1127, 1994.				
52	Petrokovski "Conserved Sequence Features of Inteins (Protein Introns) and Their Use in Identifying New Inteins and Related Proteins", Protein Science, 3: 2340-2350, 1994.				
53	Petrokovski "Modular Organization of Inteins and C-Terminal Autocatalytic Domains", Protein Science, 7: 64-71, 1998.				
54	Porter et al. "Hedgehog Patterning Activity: Role of A Lipophilic Modification Mediated by the Carboxy-Terminal Autoprocessing Domain", Cell, 86: 21-34, 1996.				
55	Porter et al. "Cholesterol Modification of Hedgehog Signaling Proteins in Animal Development", Science, 274(5285): 255-259, 1996.				
56	Sano et al. "Streptavidin-Containing Chimeric Proteins: Design and Production", Methods in Enzymology, 326(19): 305-311, 2000.				
57	Sano et al. "Genetic Engineering of Streptavidin, A Versatile Affinity Tag", Journal of Chromatography B, 715: 85-91, 1998.				
58	Schmidt et al. "Molecular Interaction Between the Strap-Tag Affinity Peptide and Its Cognate Target, Streptavidin", Journal of Molecular Biology, 255: 753-766, 1996.				
59	Schmidt et al. "The Random Peptide Library-Assisted Engineering of A C-Terminal Affinity Peptide, Useful for the Detection and Purification of A Functional Ig Fv Fragment", Protein Engineering, 6(1): 109-122, 1993.				
60	Sheibani "Prokaryotic Gene Fusion Expression System and Their Use in Structural and Functional Studies of Proteins", Preparations in Biochemistry & Biotechnology, 29(1): 77-90, 1999.				
61	Shingledecker et al. "Molecular Dissection of the Mycobacterium Tuberculosis RecA Intein: Design of A Minimal Intein and of A Trans-Splicing System Involving Two Intein Fragments", Gene, 207: 187-195, 1998.				
62	Skerra et al. "Applications of A Peptide Ligand for Streptavidin: The Strep-Tag", Biomolecular Engineering, 16: 79-86, 1999.				
63	Stoddard et al. "Breaking Up Is Hard to Do", Nature Structural Biology, 5(1): 3-5, 1998.				
64	Vorm et al. "Improved Resolution and Very High Sensitivity in MALDI TOF of Matrix Surfaces Made by Fast Evaporation", Analytical Chemistry, 66(19): 3281-3287, 1994.				
65	Wilchek et al. "An Overview of Affinity Chromatography", Methods in Molecular Biology, 147: 1-6, 2000.				
66	Xu et al. "The Mechanism of Protein Splicing and Its Modulation by Mutation", The EMBO Journal, 15(19): 5146-5153, 1996.				
Signature				Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>. Applicant's unique citation designation number (optional). <sup>2</sup>. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. this collection is estimated to take 2 hours to complete, including